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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO.            |
|--|-------------|----------------------|----------------------------------|-----------------------------|
| 10/652,861   | 08/29/2003  | Ulrich Busch         | 117163.00087                     | 1001                        |
| 21324 7590 05/07/2007<br>HAHN LOESER & PARKS, LLP<br>One GOJO Plaza<br>Suite 300<br>AKRON, OH 44311-1076 |             |                      | EXAMINER<br>FLORY, CHRISTOPHER A |                             |
|  |             |                      | ART UNIT<br>3762                 | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>05/07/2007  | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/652,861    | <b>Applicant(s)</b><br>BUSCH ET AL. |  |
|                              | <b>Examiner</b><br>Christopher A. Flory | <b>Art Unit</b><br>3762             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
  - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The new title of invention filed 5 September 2006 is sufficiently descriptive to overcome the objection of the previous Office Action filed 5 June 2006.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 2 both require the stimulation unit to be "actuated with regard to an interatrial conduction time." Applicant has asserted in the reply filed 5 September 2006 on page 12, paragraph 3, that the Limousin reference only discloses one single atrial circuit, and therefore there cannot be anything like an interatrial interval between activation of the right and left atria. It is noted in response that claims 1 and 2 of the instant application, as written, also only disclose sensing unit(s) for a single (first) atrium, and therefore also lack the ability to determine an interatrial conduction time as later required in the claim. The disclosure of "at least one sensing unit" is stated in relation to a first atrium, so that even the inclusion of multiple sensing units can only be

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read as to provide additional sensing abilities within the first atrium and not a second atrium. Therefore, the instant application lacks the ability to sense or actuate with regard to an interatrial conduction time.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a sensing unit to sense events of the second atrium so as to facilitate measuring of an interatrial conduction time.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The following rejections are based on prior art, which can be applied to the claims as to the best of the understanding of the Examiner.

Claims 1-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161).

In regards to claims 1 and 2, Examiner is interpreting both a "sensing unit" and "stimulation unit" to be electrodes, or in the alternative the circuitry required to perform sensing and stimulation. Limousin teaches of a double atrial triple chamber cardiac pacemaker, comprising at least one sensing unit for sensing events of a first atrium and a first ventricle (see for example col. 3 lines 50-53), at least one stimulation unit that is adapted to produce stimulation pulses to a second atrium (see for example col. 2 lines 37-43 and the first ventricle (see for example col. 2 lines 37-43), a control unit (col. 3 lines 17-27). Examiner takes the position that it is inherent in the system as taught by Limousin to provide ventricular stimulation pulse in the absence of sensed ventricular event after an atrial sensed event triggers a ventricular escape interval (see for example col. 4 lines 38-49), since this is the reason for providing ventricular stimulation (see for example col. 4 lines 5-7), or in the alternative it is well known in the art to stimulate the ventricle in the absence of sensed ventricular event at the conclusion ventricular escape interval, and it would have been obvious to one having ordinary skill in the art to modify the system as taught by Limousin to provide ventricular stimulation under such conditions. Examiner also takes the position that Limousin teaches of stimulating a second atrium in regards to interatrial conduction time (16) if the stimulation pulse is not inhibited (see for example col. 6 lines 4-13).

Further in regards to claims 1 and 2, Examiner takes the position that Limousin teaches that the delivery of a stimulation pulse to a second atrium is suppressed if a ventricular sensed event occurs in a crosstalk/listening window (see for example col. 5 lines 61-67 and col. 6 lines 1-4), and if the time between the previous ventricular event

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that occurred outside of the listening window and the time of the next possible ventricular event can be measured by the system and determined to be greater than what would be expected for an acceptable time period/interval (col. 6 lines 17-20), similarly to the process Limousin teaches of for measurements of sensed atrial signals (see for example col. 5 lines 40-60). Or in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Limousin to include a timing of an interval between such ventricular events and comparing it to a predetermine value/interval.

Further regarding claim 2, Limousin teaches of suppressing the delivery of a stimulation pulse to the second atrium (see for example col. 5 lines 61-67 and col. 6 lines 1-4) and inherently has the ability to do so when the system is working the maximum stimulation rate, since there no is teaching that it is not capable of doing such.

In regards to claims 3 and 7, again Examiner interprets "sensing unit" to be an electrode or the circuitry required for sensing. Limousin teaches of sensing in the right atrium (col. 3 lines 53-63), which Examiner interprets broadly to include a separate sensing unit. Or in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a separate (multiple sensing units), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Further, in regards to claims 3 and 7, Examiner takes the position that the Limousin system is capable of suppressing the stimulation of the second atrium in light of a signal which is characteristic of a left atrial sensed event (see for example col. 3 lines 53-63),

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or in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Limousin to suppress the stimulation of the second atrium in light of left atrial sensed event (see for example col. 3 lines 63-67 and col. 4 lines 1-5).

In regards to claims 4-6 and 8-16, Examiner take the position that Limousin system teaches of calculating the time spacing between a ventricular event and a planned ventricular stimulation, and further comparing the calculated timed spacing to a predetermined value (see for example col. 6 lines 17-20 and col. 5 lines 40-60). Or in the alternative, the calculating of a interval between ventricular events and further comparing the events to a predetermined time is well know in the art and would have been an obvious modification to the Limousin system to one having ordinary skill in the art at the time of the invention.

### ***Response to Arguments***

8. Applicant's arguments, see page 8 paragraph 5 through page 9 paragraph 3, filed 5 September 2006, with respect to the 35 U.S.C. §112, 1<sup>st</sup> paragraph rejection of claims 3 and 7 have been fully considered and are persuasive. The §112, 1<sup>st</sup> paragraph rejection of claims 3 and 7 has been withdrawn.

9. Applicant's arguments, see page 9, paragraph 4 through page 10, paragraph 3, filed 5 September 2006, with respect to the 35 U.S.C. §112, 2<sup>nd</sup> paragraph rejection of claim 1 have been fully considered and are persuasive. The §112, second paragraph rejection of claim 1 has been withdrawn in light of the fact that Applicant has clarified

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that two conditions must be fulfilled simultaneously in order to inhibit second atrium stimulation.

10. Applicant's arguments filed 5 September 2006 have been fully considered but they are not persuasive. Claims 1-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161).

Applicant argues that Limousin only discloses one single atrial circuit and therefore cannot provide anything like an interatrial interval, stated as an essential feature of claims 1 and 2. As is noted above in the §112 rejection, the instant application also discloses only a single atrial sensing circuit and is therefore held to also fail to disclose the ability to provide an interatrial interval. Furthermore, Limousin clearly discloses in the abstract and in column 5, lines 39-65--cited by the Applicant—that the Limousin device is capable of calculating an A-A interval, and further that the PP interval is read as an interatrial interval as well.

Applicant also argues that the crosstalk window of the instant application is not identical or equivalent to the listening window of Limousin. However, the Examiner maintains that the crosstalk and listening windows are equivalents, since both relate to a post-atrial ventricular sense on the ventricular channel of the system. As such, the Examiner fails to see any structural or functional variance between the two circuits, and considers them to be equivalents in the art.



***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

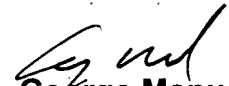
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

16 April 2007

  
**George Manuel**  
Primary Examiner